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| 09/747,078      | 12/21/2000  | Woodrow C. Monte     | 32166.00002         | 2298             |

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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/747,078

Applicant(s)

MONTE, WOODROW C.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,3 and 6-41 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 6-9, 11, and 13-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is in response to Applicant's (remarks/Arguments) filed on January 31, 2005 wherein no claims are amended, cancelled, or newly submitted.

Currently, claims 2, 3, and 6-41 are pending in this application.

It is noted that claims 10 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, submitted March 12, 2002.

Claims 2, 3, 6-9, 11, and 13-41 are currently under examination on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 6-9, and 13-41 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular and specific agent such as a lactose-converting enzyme to be added into a particular food or cosmetic composition, employed in the claimed method herein, does not reasonably provide enablement for any substances or compounds represented by "an active" and "a food or cosmetic composition", "composition is at or above a temperature that would denature the active, wherein some of the active is not denatured and imparts a beneficial effect to the composition", "a lactose-converting active" and "a lactose-

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containing composition", recited in the claims herein, of record in the previous Office Action July 28, 2004.

These recitations, "an active" and "a food or cosmetic composition", "composition is at or above a temperature that would denature the active, wherein some of the active is not denatured and imparts a beneficial effect to the composition", "a lactose-converting active" and "a lactose-containing composition", are seen to be merely functional language.

Moreover, note that any "active" and "food or cosmetic composition", "composition is at or above a temperature that would denature the active, wherein some of the active is not denatured and imparts a beneficial effect to the composition", "a lactose-converting active" and "a lactose-containing composition" broadly encompass those known and unknown substances or compounds or compositions having the functions recited in the claims, as of the instant filing date, as well as those unknown and future known substances or compounds or compositions yet to be discovered.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims;

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(6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method for adding a device to a food or cosmetic composition.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims read on those known and unknown any substances or compounds or compositions represented by “an active” and “a food or cosmetic composition”, “composition is at or above a temperature that would denature the active, wherein some of the active is not denatured and imparts a beneficial effect to the composition”, “a lactose-converting active” and “a lactose-containing composition” as of the instant filing date.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does “little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate”. The CAFC further clearly states that “[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials” at 1405(emphasis added), and that “It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a

fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

In the instant case, any substances or compounds represented by "an active" and "a food or cosmetic composition", "composition is at or above a temperature that would denature the active, wherein some of the active is not denatured and imparts a beneficial effect to the composition", "a lactose-converting active" and "a lactose-containing composition". Hence, these functional recitations read on any compounds that might have the recited functions. However, the specification merely provides the specific and particular actives in specific and particular food or cosmetic compositions.

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the food or cosmetic art is unpredictable, requiring each embodiment to be individually assessed for physical, chemical and physiological activity. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of

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the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co.* Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the food or cosmetic compositions herein.

Moreover, as indicated above, these recitations broadly encompass those known and unknown substances, compounds, or compositions as of the instant filing date, as well as those future known compounds yet to be discovered. Thus, those unknown or future known compounds must require additional or future research to discover, establish or verify their usefulness. Therefore, the skilled artisan has to exercise **undue experimentation** to practice the instant invention.

The presence or absence of working examples and the quantity of experimentation necessary:

As discussed above, only those specific and particular actives employed in the composition and the claimed method in the specification. Moreover, it is noted that only a **single** example with two compositions #1 and #2 is disclosed in the specification (see page 19-22 of the specification). Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active agents or compounds in the claimed composition. See MPEP § 716.02(d).

Thus, the specification fails to provide sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

*Genentech*, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test all active encompassed in the instant claims employed in the claimed method, with no assurance of success.

Applicant's arguments filed January 31, 2005 with respect to this rejection made under 35 U.S.C. 112, first paragraph, for lack of full scope of enablement have been fully considered but are not deemed persuasive. These remarks are believed to be adequately addressed by the rejection presented above.

Moreover, the court of *In re Curtis* held that “a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operability .....of any other species.” (emphasis added, see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274, Fed. Cir. 2004). The court of *Noelle v. Lederman* also pointed out



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that generic claim to anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, and no description of human CD40CR antigen. The court further pointed out that attempt to "define an unknown by its binding affinity to another unknown" failed. See 355 F.3d 1343, 69 USPQ2d 1508, Fed. Cir. 2004.

In this case, the claimed method herein is deemed not to adequately described. Thus, ordinary artisans could not predict the operability of any other species of "an active" and "a food or cosmetic composition", "composition is at or above a temperature that would denature the active, wherein some of the active is not denatured and imparts a beneficial effect to the composition", "a lactose-converting active" and "a lactose-containing composition".

For the above stated reasons, said claims are properly rejected made under 35 U.S.C. 112, first paragraph, for lack of full scope of enablement.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 6-9, and 13-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, of record in the previous Office Action July 28, 2004.

The recitation, "active" in claim 2 render claims 2, 4-9, and 13-41 indefinite. Moreover, the recitation "would" in claim 2 render these claims indefinite. Claim 2 recites the limitation "the beneficial effect", which render these claims indefinite as discussed in the previous Office Action July 28, 2004.

### ***Response to Argument***

Applicant's remarks filed January 31, 2005 with respect to this rejection have been fully considered but are not deemed persuasive as further discussed below.

Again, Applicant asserts that "an active" in claim 2 and "another substance" in claims 15 and 25, "would" and "the beneficial effect" are defined in the specification. Applicant argues that "these meanings are plainly set forth in context of the claims and specification". Applicant's assertion and argument are not found convincing. As pointed out in the previous Office Action, noted in MPEP 2111, during patent examination, claims are given their **broadest** reasonable interpretation. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim. However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).

Hence, one of ordinary skill in the art could not interpret the **metes and bounds** of the patent protection desired as to "active" and "another substance" encompassed thereby.

Moreover, the recitation "would" in claim 2 render claims 2, 3, 4-9, and 13-41 indefinite, contrary to Applicant's assertion that "There is nothing indefinite about the

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use of "would", since the recitation "would" renders the uncertainty if the temperature denatures the active herein. According to the ordinary and customary meaning of "would" provided by a dictionary: "wished" or "desired" for example (see the definition provided by Merriam-Webster's Collegiate Dictionary, Tenth Edition, 1998, page 1365, PTO-892), Thus, the claims herein are indefinite as to whether the active herein certainly denatures at the temperature or merely as wished or desired.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 6-9, 11, 13-19, 22-26, 28, and 31-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Monte (5,707,843) of record in the previous Office Action July 28, 2004.

Monte discloses a method therein including steps: adding (including) an enzyme or lactose-converting enzyme to a composition, heating the composition therein to a temperature to a selected temperature for a time sufficient to at least pasteurize the composition or the dairy product therein (see col.2 lines 18-22 and claim 4 step c at line 228-29, in particular) which reads on the instant denaturing temperature that denatures an active broadly, and packaging the enzyme composition, or cooling the enzyme composition. Monte also discloses the lactose enzyme composition therein is a food

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product such as a milk product. Moreover, Monte discloses that the lactose therein can be converted from 50% to 99% and that the composition has pH of 6.0 or less. See abstract, col.1 lines 21-39, col. 2. lines 7-10 and 18-49, col.5-6, in particular col.5 lines 36-48, and claims 4-8. The packaged product of Monte or packaging the enzyme composition of Monte reads on the instant container comprising the composition. Monte also discloses the method or process for sterilizing a dairy product (see col.1 line 63 to col.2 line 12).

Thus, the disclosure of Monte anticipates claims 2, 6-9, 11, 13-19, 22-26, 28, and 31-41.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-22, 23, 27, 29-30 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monte (5,707,843) in view of Monte (5,578,336 and 5,424,299) of record stated in the Office Action dated July 28, 2004.

The same disclosure of Monte has been discussed above.

Monte does not expressly disclose providing a tablet including the active, and the tablet being coated with sugar and that the food may be an enteral food. Monte does

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not expressly disclose that the heating temperature is 180F or higher, and that the outer surface of the tablet is treated with gamma rays.

Monte (5,578,336) discloses that the coating of the enzyme or vitamin candy composition therein is sugar or sugarless sweetener in a form as oral ingestion of tablets. See abstract, col.1 lines 15-18, and col.2 especially lines 65-67, and Examples.

Monte (5,424,299) discloses that the food containing enzyme composition therein is an enteral food. See abstract, col.1 lines 64-66, Examples and claims 1-9.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a tablet including the active, the tablet being coated with sugar and prepare the particular food, an enteral food, and to heat the composition to 180F or higher, and to treat the tablet with gamma rays.

One having ordinary skill in the art at the time the invention was made would have been motivated to provide a tablet including the active, the tablet being coated with sugar and prepare the particular food, an enteral food, since these steps herein i.e., providing a tablet including the active, the tablet being coated with sugar and preparing the particular food, an enteral food, are considered well within conventional skills in food science, involving merely routine skill in the art, and also taught by Monte (5,578,336 and 5,424,299) .

Moreover, the determination of how high the temperature to be raised in the heating based on the known denaturing temperature of the active given is considered well within well within conventional skills in the art, involving merely routine skill in the

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art since Monte (5,707,843) discloses the heating step herein. Further, using gamma rays for sterilizing a tablet is well known in the art.

Thus, the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

### ***Response to Argument***

Applicant's remarks filed January 31, 2005 with respect to the rejection made under 35 U.S.C. 102(b) and the rejection made under 35 U.S.C. 103(a) in the previous Office Action have been fully considered but are not deemed persuasive as further discussed below.

Applicant asserts that "[t]he invention allows for, among other things, the addition of an active to a substance while the substance is at a temperature that would normally denature the active and, utilizing the invention, the active is not denatured". In contrast to Applicant's assertion, the instant claims are unclear as to what active and composition to be denatured. Moreover, as discussed above, the term "would" renders the uncertainty whether the active herein certainly denatures at the temperature or merely as wished or desired.

Further, Applicant's arguments in the six points regarding the Monte's disclosure in '843, Monte's disclosure in '843 are not persuasive. First, in regard to Applicant's "1" "3" and "4", the claims 2, 6-9, 11, 13-19, 22-26, 28, and 31-41 are not limited to any temperature at which an active is added to a composition and the instant claims are unclear as to what active and composition to be denatured, as pointed out above. Second, regarding Applicant's "2", the teachings at col.1 lines 21-39 clearly read on the

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instant invention, "adding lactase enzyme to a milk product and then heating the milk product to at an elevated in excess of about 140 degree...." (see col.1 lines 21-26). In contrast to Applicant's assertion in "5" and "6", that the cited prior art "teaches away any aspect of the claimed method to make a composition", Monte discloses a method therein including steps herein: adding (including) an enzyme or lactose-converting enzyme to a composition. Moreover, it is unclear and confusing as to what and which is a composition to be made by the claimed method that Applicant asserts.

Furthermore, the record contains no clear and convincing evidence of nonobviousness or unexpected results for the combination method herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 3, 6-9, 11, 13-19, 22-26, 28, and 31-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,707,843 of record stated in the Office Action dated July 28, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method comprising the same method steps as discussed in the 102(b) rejection set forth above.

Thus, the instant claims 2, 6-9, 11, 13-19, 22-26, 28, and 31-41 are deemed to anticipate the claims 1-8 of U.S. Patent No. 5,707,843.

In view of the rejections to the pending claims set forth above, no claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

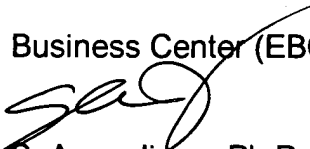


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.  
Primary Examiner  
Art Unit 1617  
May 6, 2005